REMARKS

Claims 1, 3-9, 11-22, and 25-33 are pending in the application. Claims 9, 11-22 and 25-33 are withdrawn from consideration. Claims 1 and 3-8 are rejected. By the present amendment, claims 1, 3-8, 21, 22, 25-29, and 31 are amended, claims 9-20, and 30 are hereby canceled without prejudice and disclaimer, and new claims 34-38 are hereby added. In addition, the specification is amended to add sequence identifiers and to correct typographical errors. The amendments and claims are supported by the original application and thus add no new matter.

In view of the above-described amendments and following remarks, applicants respectfully request reconsideration of claim 1, 3-8, and consideration of new composition claims 34-36. Applicants also respectfully request rejoinder and reconsideration of the process claims 21, 22, 25-29, 32, and 33, and the composition claim 31. Applicant also respectfully requests consideration of new process claims 37 and 38.

Response to Restriction Requirement

Applicant confirms election, with traverse, of the invention of Group 1, claims 1, 3-8, and 31 drawn to a chimeric or multivalent peptide.. Applicant also confirms election of the HER-2 B epitopes of SEQ ID NO: 6 and SEQ ID NO: 42, and the T helper epitope of SEQ ID NO: 17.

The Office makes the case that the claims of groups I, II, and III are distinct:

> Inventions of Groups I and II and the inventions of Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practic ed with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely a composition comprising a chimeric peptide comprising one or more B cell epitopes .....can be used in a materially different process of using that product, such as by the process of using the product to purify an antibodies that bind the chimeric peptide by affinity chromatography. (See the linking paragraph of page 6 and page 7 of the Office Action.

Applicant submits that restriction is not proper in this instance. MPEP § 803 states the requirement for a *proper* restriction.

> There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; **and (B) There must be a serious burden on the examiner if restriction is required.**

(MPEP§ 803, citations omitted, emphasis added.) Thus, there are *two* requirements for restriction: independence or distinctness ***and*** a serious burden. Both are required; independence or distinctness without a serious burden is not sufficient to justify restriction. Section 803 explicitly sates that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though in includes claims to independent or distinct inventions."

Applicant respectfully submits that restriction is not proper in this case. While the claims of Groups I and III may satisfy the Office's requirements for distinctness or independence, their consideration would not result in a serious burden on the Office, particularly since the various pharmceutically acceptable vehicles have been removed from process claims 27-29.

In accordance with the provisions of MPEP § 821.04, applicant also respectfully requests rejoinder of the withdrawn process claims 21, 22, 25-29, 32 and 33 (Group III). With respect to claim 26, applicant elects breast cancer.

Applicant also submits that since a search for a multivalent peptide or a mixture of chimeric peptides in which the sequence of one of the HER-B cell epitopes is SEQ ID NO: 6 and the sequence of another of the HER-2 B cell epitopes is SEQ ID NO: 42 should also uncover a multivalent peptide of mixture of chimeric peptides in which the sequences of 3 of the HER-2 B cell epitiopes are SEQ ID NO; 6, 42 and 9, examination of the composition of amended claim 31 would not result in a serious burden to the Examiner. Accordingly, applicant respectfully requests rejoinder of claim 31.

Objections to the Disclosure

As requested by the Patent Office, applicant submits herewith a new set of drawings including a new Figure 5 and a new Figure 8.

As suggested by the Patent office applicant has amended the specification on page 30 (line 11), page 31 (line 2 and the legend of Table 4) and page 32 (line 4) to add the sequence identifier SEQ ID NO: 20 for the sequence GSPL.

As suggested by the Patent Office, applicant has added the symbol "TM" to the trademarks Vydac, Celite, and Slide-a-lyzer as found on pages 19 and 20 of the specification. Applicant has also corrected the spelling of "current" at page 17, line 31, added the figure number at page 27, line 9, added a space between "linker" and "(MVFN4)" on page 32, line 4, and between "medium" and "(Blowitaker)" on page 34, line 26.

Applicant submits that these amendments overcome the objections to the drawings and specification.

Claim Objections

As suggested by the Patent Office applicant has amended claim 6 to recite wherein each of said 2 or more HER-2 B cell epitopes are different from the others. Applicant submits that the amendment overcomes the objection to claims 6-8.

35 USC § 112

Claims 1 and 3-8 are rejected under 35 USC § 112, first paragraph, "as failing to comply with the written description requirement." (See page 17 of the Office Action.) Claim 1 has been amended to recite a chimeric peptide in which the sequence of the HER-2 B cell epitope is SEQ ID NO: 1, 4, 6, 9, or 11, and wherein the sequence of the Th epitope comprises a sequence selected from the group consisting of SEQ ID NO: 13, 14, 15, 16, 17, 18, and 19, and a linker that comprises from 1 to 15 amino acids. In addition claim 6, has been amended to recite a multivalent peptide in which the sequence of the 2 or more HER-2 B cell epitiopes is SEQ ID NO: 1, 4, 6, 9, 11, and 42, and wherein the template comprises two strands of alternating leucine and lysine residues connected by a linker consisting of one to 15 amino acids. Since one of ordinary skill in the art would know and appreciate that applicants were in possession of such chimeric and multivalent peptides at the time the application was filed, claims 1, and 3-8 meet the written description requirement of § 112. Accordingly, applicant requests that the rejection be withdrawn.

Claims 1, and 3-8 are also rejected under 35 USC §112, first paragaph, because the specification "does not reasonably prove enablement for making the claimed compositions..." (See page 24 of the Office Action). Applicants submit that the claims 1, and 3-8, as amended, are fully enabled, and request withdrawal of the rejection.

Claims 1, and 3-5, are rejected under 35 USC § 112, second paragraph, "as being indefinite". (See page 37 of the Office Action.) As amended claim 1, no longer recites "said HER-2 B cell epitope being from 15 to 40 amino acids in length." Accordingly applicant submits that claims 1 and 3-5 are definite, and requests that the rejection be withdrawn.

§ 103 Rejections

Claims 1 and 3-5 are rejected under 35 USC § 103(a) as being unpatentable over Woodbine (Doctoral Dissertation: "BIOLOGICAL EFFECTS OF ANTI-PEPTIDE ANTIBODIES AGAINST THE HER-2/NEU RECEPTOR TYROSINE KINASE IMPLICATIONS FOR THERAPY FO HUMAN BREAST CANCER:, The Ohio State Univesity, 1997)(hereinafter "Woodbine") in view of Hawerth et al. (British Journal of Cancer. 1993 68: 1140-1145)(hereinafter "Hawerth et al.")

Claim 1 has been amended to recite a chimeric peptide in which the sequence of the HER 2-B cell epitope is SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 9 or SEQ ID NO: 11. Neither Woodbine nor Hawerth et al. teach or suggest such a chimeric peptide. Accordingly, Woodbine and Hawerth et al do not render the chimeric peptide of claim 1 obvious. Claims 3-5 depend from claim 1 and, for the same reasons, are not obvious in view of Woodbine and Hawerth et al.

Applicants submit that claims 1, and 3- 8, as amended, and new claims 34 and 35 are now in condition for allowance. Applicant also submits that withdrawn claims 21, 22, 25-29, 31, and 32, as amended, and new process claims 37 and 38 are now in condition for rejoinder and allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the pending claims or the drawings, he is encouraged to call the undersigned at (216) 622-8416.

Respectfully submitted,

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